

IVAC[®]

CORE•CHECK[®]

Tympanic Thermometer System

Model 2090

Directions for Use

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About the System

This manual is a guide for using the CORE•CHECK® Tympanic Thermometer System Model 2090. The CORE•CHECK® Thermometer is designed to measure infrared energy emitted from the tympanic membrane. Infrared energy is generated by the vibration and movement of molecules in all matter. As temperature increases so does molecular activity, causing an increase in the radiation of infrared energy.

Infrared energy emitted from the tympanic membrane in the ear canal provides an excellent measurement of the body's core temperature. The blood supply for the tympanic membrane is common with the hypothalamus, the area of the brain that regulates body temperature.

The CORE•CHECK® Thermometer is positioned in the external auditory canal. The thermometer senses infrared radiation emitted from the surface of the tympanic membrane and surrounding tissue. This reading is quickly processed through the CORE•CHECK® Thermometer technology to provide an accurate measurement of core body temperature.

The CORE•CHECK® Tympanic Thermometer System includes the thermometer, Probe Cover Dispenser - Model 2992, Home Base - Model 2993, and Probe Cover Bracket - Model 2994. The thermometer uses ALARIS Medical Systems® Disposable Probe Covers, Model P90.

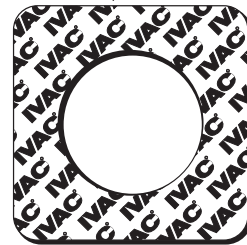
For additional information, contact your ALARIS Medical Systems® representative.

Feature Summary

Thermometer Features

- Accurate, non-invasive determination of core temperature
- Temperature measurement within 3 seconds
- Anti-theft feature
- Durable by design and construction
- User-selectable Celsius or Fahrenheit temperature readings
- Display backlight for low-light conditions
- Powered by a single 9-volt battery
- Home base holds thermometer and dispenser
- Disposable probe covers and probe cover detectors reduce the risk of cross-contamination
- Dispenser conveniently stores and dispenses probe covers
- Thermometer performs a self-test

Disposable
Probe Cover



PROBE COVER BRACKET

Attaches to the wall and holds a box of five probe cover packets.

HOME BASE

Holds thermometer and dispenser, also resets the anti-theft feature.

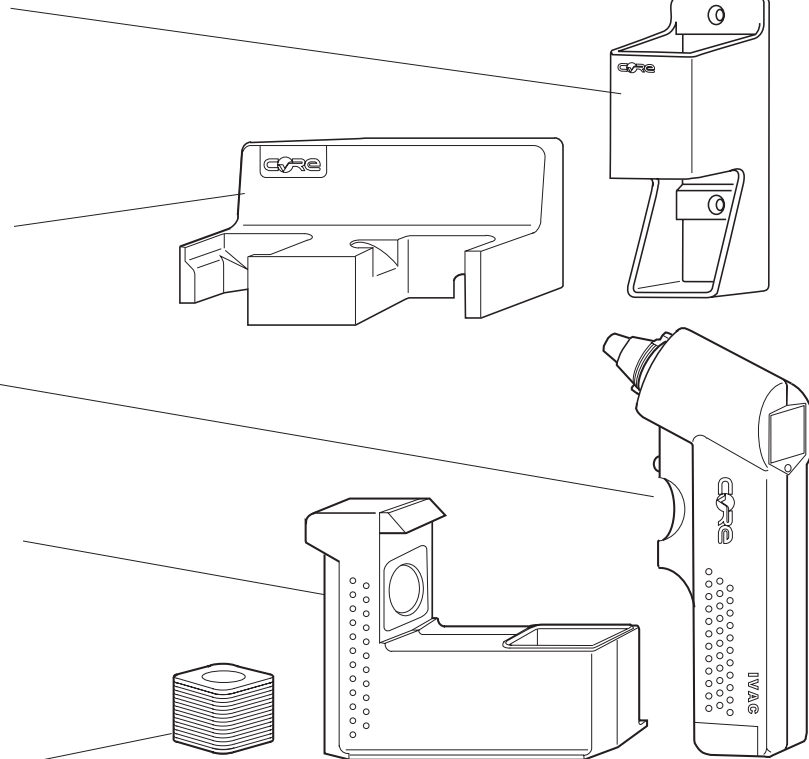
THERMOMETER

DISPENSER

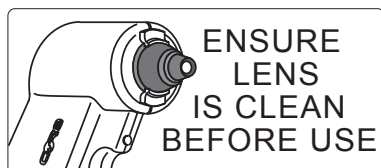
Holds and dispenses P90 probe covers. Combines with thermometer to provide a hand-held unit.

DISPOSABLE PROBE COVERS

Reduce the risk of cross-contamination and easily loads onto thermometer probe tip.



Definitions



Cleaning Advisory.



Alkaline battery used.



Anti-Theft notification.



Instructions for probe cover dispenser.

External Auditory Canal

A narrow, tube-like passage through which sound enters the ear, also named an external auditory canal.

Infrared Energy

Relating to the range of invisible radiation wavelengths from 750 nanometers. Generating, using, or sensitive to infrared radiation.

Molecular Activity

Temperature is a measure of molecular motion. Pressure is a measure of molecular activity. The higher the pressure, the faster the molecules are moving and greater energy equals greater temperature.

Tympanic Membrane

The membrane in the ear that vibrates to sound.



Conformance to the Medical Device Directive 93/42/EEC



Manufactured Date; expressed in four digits as the year and two digits as the month.



Attention: Refer to accompanying documentation.

IPX1

Indicates degree of protection, fluid ingress.

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To ensure proper performance of the CORE•CHECK® Thermometer and to reduce potential injury, observe the following precautions.

Warnings and Cautions

Definitions

WARNING

A warning is an alert to potential serious outcomes (death, injury or serious adverse events) to the patient or user.

CAUTION

A caution is an alert to take special care for the safe and effective use of the device.

Cautions

CAUTION

Do not autoclave or immerse the CORE•CHECK® Thermometer as damage will occur.

CAUTION

Operating the CORE•CHECK® Thermometer near equipment which radiates high energy frequencies (for example electrosurgical/cauterizing equipment), may affect temperature readings.

CAUTION

If unusually low or high temperature readings are obtained, remove the probe cover, verify the probe lens is clean, shiny, dry, undamaged, and free of debris. Attach a new probe cover and repeat measurement.

CAUTION

Keep lens clean. Lens should be cleaned with a dry-lint free scrub or tissue. Replace lens if it remains cloudy.

CAUTION

Damage may occur if alcohol or acetone is used.

Instrument Features

Figure 1

CORE•CHECK® Tympanic Thermometer System

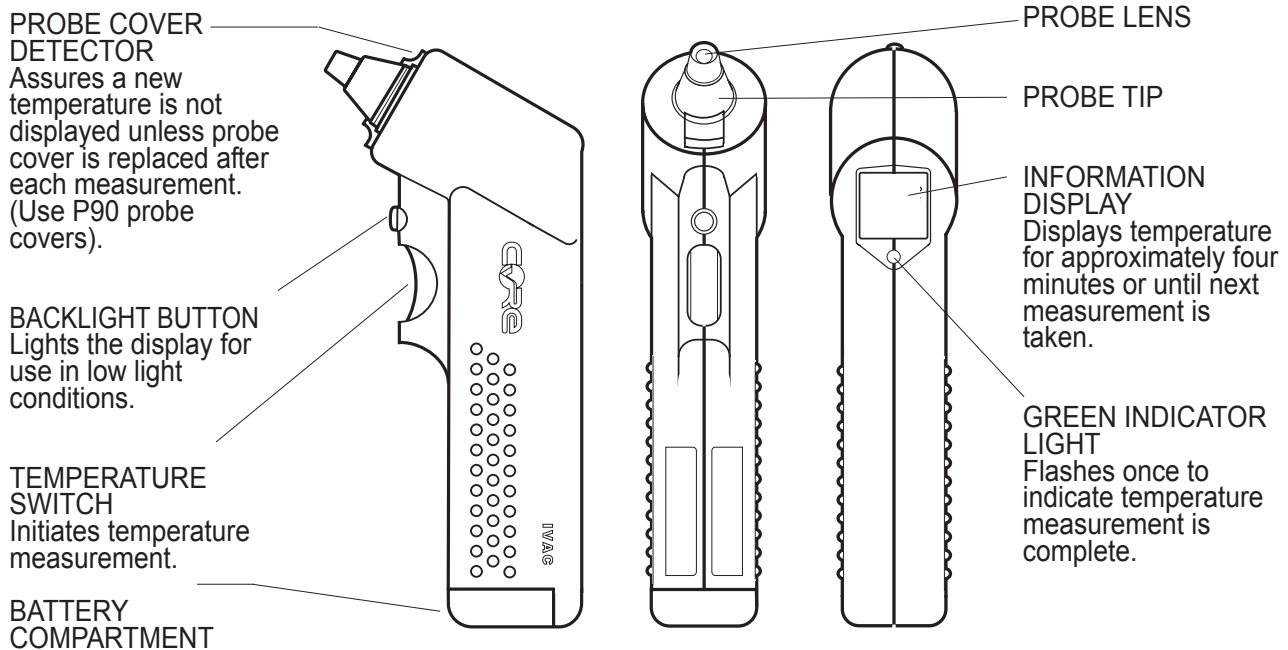
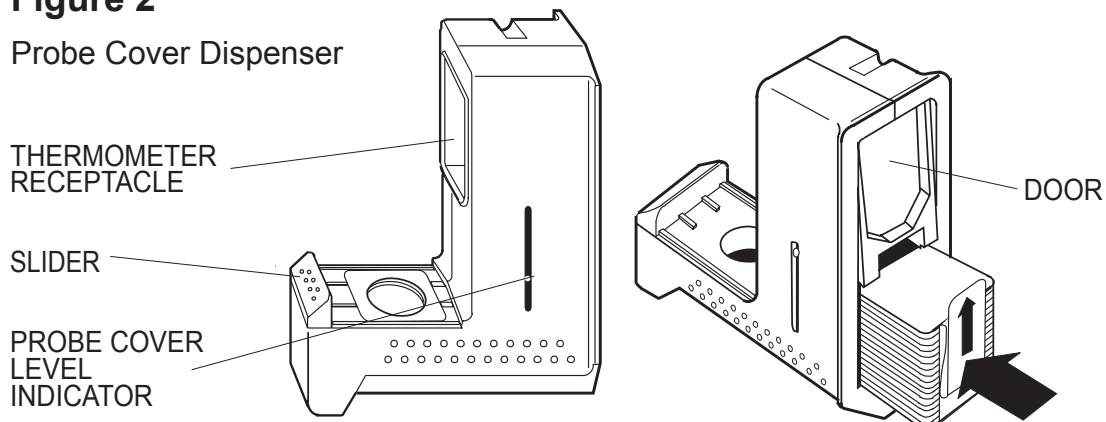


Figure 2

Probe Cover Dispenser



Setup Procedure

1. Carefully unpack the CORE•CHECK® Tympanic Thermometer System and ensure the thermometer, dispenser, and home base are undamaged. Packaging will include a battery, battery compartment cover, extra probe tips and a probe cover wall bracket.
2. Set Temperature mode: Set thermometer to Celsius (°C) or Fahrenheit (°F) by sliding the recessed switch located on left side of the battery compartment. Use a small screwdriver or pen tip to slide the switch into position (°F = toward the outside; °C = toward the center).
3. Install Battery: Place a 9-volt alkaline battery into the compartment as shown in Figure 3 and snap connector onto battery terminals.
4. Attach battery compartment cover. Orient the cover's arrow as shown in Figure 3. Slide cover over opening until cover locks in place. If necessary to remove the cover, begin by firmly pressing center of cover with thumb causing a corner to lift, then using the other hand, push cover at loosened corner and slide off. **DO NOT PRY COVER WITH SHARP OBJECT.**
5. Self Test: Press and hold probe cover detector flush against outer case (Figure 4). While holding, press and release temperature switch once to initiate thermometer self-test to verify both the display and thermometer's internal electronics are in working order.
 - The display is in working order if all segments momentarily appear (Figure 5). If all segments do not appear, do not use thermometer and refer to Service Information section of this manual.
 - The thermometer's internal electronics are in working order if a temperature measurement or a "lo" message appears on the display. If a numbered ERROR message appears on the display, the thermometer has detected an internal malfunction. (*Refer to ERROR message in the Information Display section of this manual.*)
6. After a successful self-test routine, the thermometer is ready for temperature measurement.
7. Home Base: The home base should be mounted to a convenient location using either adhesive tape or screws supplied with the instrument. Always store thermometer and dispenser in the home base when system is not in use, which resets the Anti-Theft feature.

Quick Guide

Set °C/°F switch mode

Install battery

Self-test

Mount home base

Setup Procedure (Continued)

Figure 3

Battery Compartment

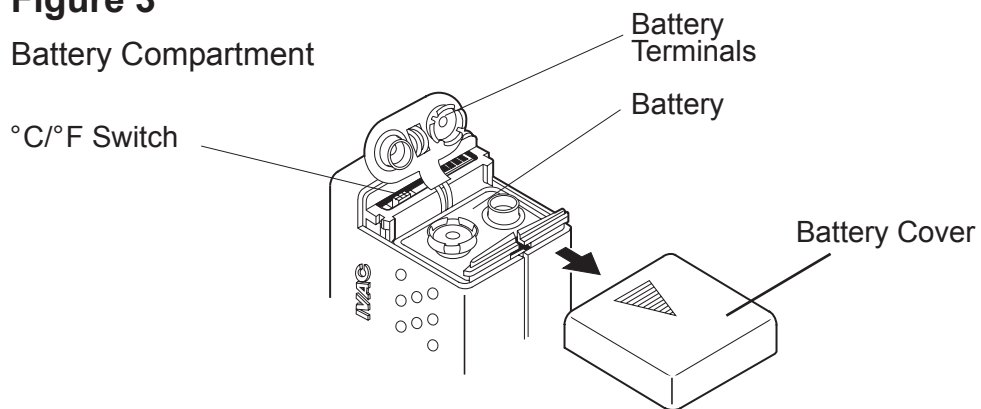


Figure 4

Probe Cover Detector

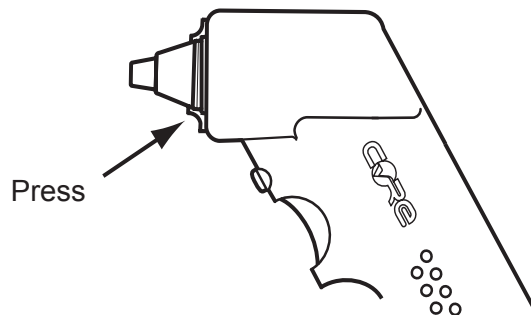
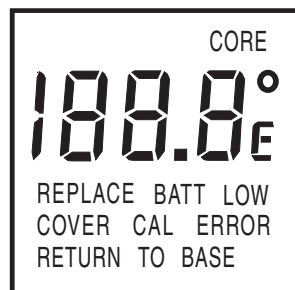


Figure 5

Information Display



OPERATING INSTRUCTIONS

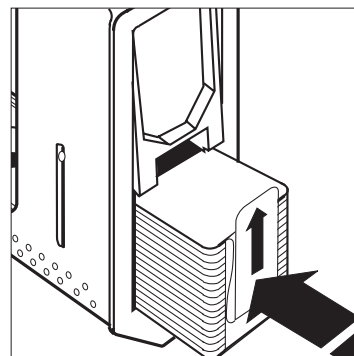
The following instructions assist in dispensing and loading probe covers onto the thermometer.

Probe Cover Dispense/Load Instructions

Probe Cover Dispenser

- Remove thermometer and dispenser from the home base.
- Press and slide dispenser door up until it locks in open position.
- Install a package of P90 probe covers into the dispenser, with arrow pointing up toward opened sliding door.
- Slide door down until locked in closed position, leaving the tab outside the door.
- Firmly grasp tab and pull it out of the dispenser.

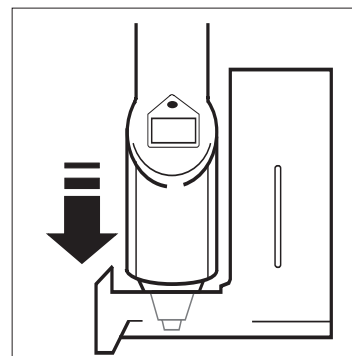
NOTE: Use only ALARIS Medical Systems® P90 probe covers with the CORE•CHECK® Thermometer. The size and thermal characteristics of the probe cover affect thermometer's performance. Inaccurate readings may occur unless recommended probe covers are used.



Load Probe Cover Onto Thermometer

- Dispense a probe cover by pushing dispenser slide completely in and slowly releasing.
- Center probe tip onto probe cover film then press firmly to engage base of probe. This will actuate the probe cover detector.
- The clear film will stretch smoothly over the entire probe. Failure to fully load the probe cover will result in a REPLACE COVER message.

NOTE: If probe cover backing is not fully seated against the base of the probe, a REPLACE COVER message will appear on the display when the measurement is initiated. If this occurs, replace the cover.

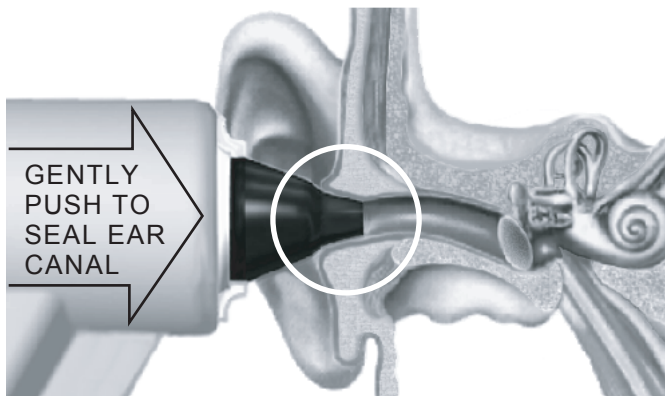


Taking A Temperature

- The most important step in obtaining accurate temperatures is correct placement of the probe tip with a P90 disposable probe cover in the patient's ear.
- Center the probe tip far enough into the ear canal to firmly seal the ear canal opening and point in the direction of the tympanic membrane. Gently restrain the head if necessary. Press and hold the temperature switch until the green light flashes and temperature reading is displayed. Correct positioning of the probe tip is necessary for accurate readings. (See Figure 6 below).

Figure 6

Positioning of Thermometer



CAUTION

Evaluate condition of the patient's ear and adjacent skin. The thermometer should not be used on patients with ear drainage, infected or chafed skin adjacent to the ear, or on patients with incisions adjacent to the ear. Such usage may increase the risk of cross-contamination.

CAUTION

Operating the CORE•CHECK Thermometer near equipment which radiates high energy frequencies (for example electrosurgical/cauterizing equipment), may affect temperature readings.

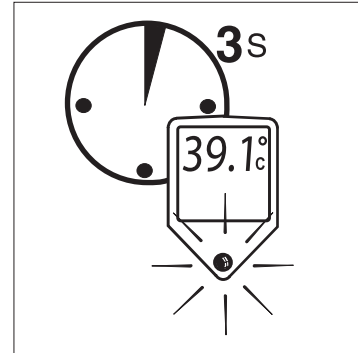
CAUTION

If an unusually low or high temperature reading is obtained, remove probe cover, verify the probe lens is clean, shiny, dry, undamaged, and free of debris. Attach a new probe cover and repeat measurement.

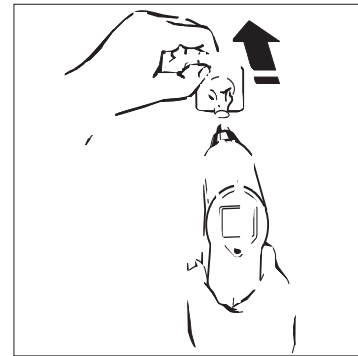
Taking A Temperature (Continued)

- Hold thermometer in place until temperature reading is displayed (Approximately three seconds). The green indicator light (below the display) will flash briefly.

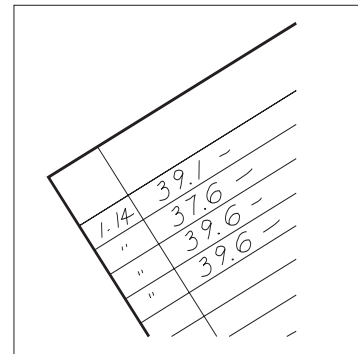
NOTE: Removal of the thermometer from the ear before a temperature is displayed will result in a low temperature reading.



- Remove thermometer from patient's ear and pull off probe cover. The used probe cover must be replaced by a new one before another measurement can be taken.



- Record the displayed temperature. Another temperature reading can be taken immediately after replacing the probe cover. The temperature will remain displayed for approximately four minutes, unless another measurement is taken.
- Store in home base.



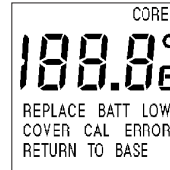
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The following examples are LCD display screens modes.

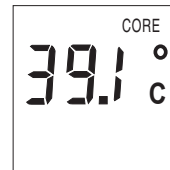
CORE • CHECK® Thermometer LCD Display Screens

Self-Test - Displays with initiation of each measurement. Inspect display to ensure all segments are operating as shown.

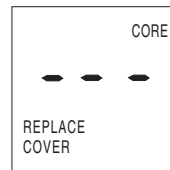
NOTE: If this self-test display continues to flash, it indicates the battery should be replaced.



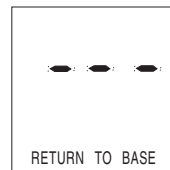
CORE - Displays with each temperature measurement.



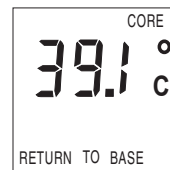
REPLACE COVER (Replace Probe Cover) - A temperature reading was initiated without a probe cover, a used probe cover, or an improperly attached probe cover. Check lens for cleanliness, attach a new probe cover, and reinitiate the measurement.



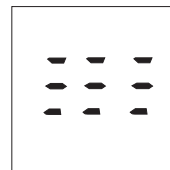
RETURN TO BASE (Anti-Theft Feature) - A limited number of measurements can be taken until thermometer displays a continuous RETURN TO BASE message. Place thermometer into home base to reset the anti-theft feature.



RETURN TO BASE - Displays as a flashing message when the limit of temperature measurements have been met. Return to base to reset.

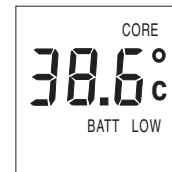


Anti-theft feature has been reset. Thermometer can be used immediately.

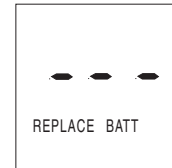


CORE • CHECK® Thermometer LCD Display Screens (Continued)

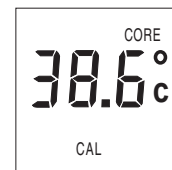
BATT LOW (Battery Low) - Battery is low and requires replacement.



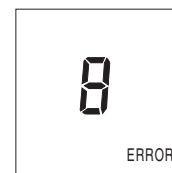
REPLACE BATT (Replace Battery) - Battery must be replaced. (Figure 3).



CAL (Recalibrate Instrument) - Indicates calibration of the thermometer should be checked. *(Refer to Maintenance section of this manual for information concerning calibration).*



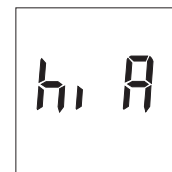
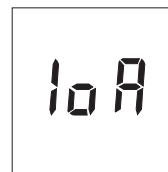
ERROR (Accompanied by a number) - Thermometer has detected an internal malfunction. Remove and reinstall battery. To perform a Self Test: Press and hold probe cover detector flush against outer case (Figure 4). While holding, press and release temperature switch once to initiate thermometer self-test to verify the display and thermometer's electronics are in working order. If error message appears again, record the number, and contact qualified service personnel.



The display messages indicates the ambient (room) temperature is outside the thermometer's operating range:

lo A - Ambient temperature is below 15.6°C (60°F).

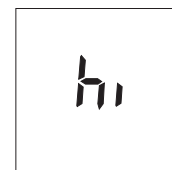
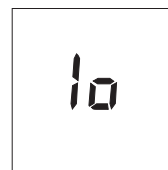
hi A - Ambient temperature is above 43.3°C (110°F).



The display messages indicates the patient's temperature is outside the thermometer measurement range:

lo - Measured temperature is below 25°C (77°F).

hi - Measured temperature is above 43.3°C (110°F).



CORE•CHECK® Thermometer Technical Service Manuals are available from **ALARIS** Medical Systems. They include routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures and/or references, and other technical information to assist service personnel in repair and maintenance of each instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel.

Specifications

Measurement Range :	25°C to 43.3°C (77°F to 110°F).
Accuracy:	±0.1°C (± 0.2°F). Meets ASTM Specifications No. E1112-86, at ambient temperature range of 18.3 to 32.2°C (65-90°F)
Response Time:	Less than 3 seconds
Battery:	Approximately 8,000 readings on one 9 volt alkaline battery, under normal use
Size:	7.5 x 1.5 x 3.0 inches (19.05 x 3.81 x 7.62 centimeters)
Weight:	8 ounces with battery (266 grams)
Case Material:	Durable, impact resistant plastic
Disposable:	ALARIS Medical Systems®, P90 Probe Covers
Humidity:	15% to 90% Noncondensing
Storage Temperature:	-35°C to 60°C (-32°F to 140°F)
Anti-Theft Feature:	40 measurements are available before return to base is displayed.
Display Messages:	Batt Low, Replace Batt, Return to Base, hi A (high ambient), lo A (low ambient), lo (low temperature), hi (high temperature and numbered error messages for internal malfunctions)

Thermometer Cleaning

- The LCD display is tested before each measurement by lighting all of its segments for a brief period. It is recommended to inspect the display during this time to ensure all segments are operating properly. The display test ends when the temperature or “**lo**” is displayed.
- ALARIS Medical Systems recommends the CORE•CHECK® Thermometer be calibrated every ten thousand readings or every six months, whichever comes first. The CAL message automatically flashes after ten thousand readings.
- Calibration must be performed using the ALARIS Medical Systems® CORE•CHECK® Thermometer Calibrator - Model 9000. (*Refer to the calibrator's operating instructions for calibration procedure*).
- If thermometer is dropped, inspect the lens and probe tip for damage. The lens and probe tip can be replaced without opening the instrument. (*Refer to the Technical Manual for procedure*). Calibrate the CORE•CHECK® Thermometer if lens replacement was required.
- The CORE•CHECK® Thermometer can be cleaned with a moist cloth warm water and a mild detergent (such as dish washing liquid) or with a variety of other agents. See Figure 7 for appropriate cleaning methods and acceptable cleaning agents for the different thermometer components.
- Do not immerse the CORE•CHECK® Thermometer.
- Frequently check the lens for cleanliness. Incorrect readings can result from debris or fingerprints. Lens should appear clear, shiny, and unobstructed from protective probe tip.

CAUTION

Do not autoclave or immerse the CORE•CHECK® Thermometer as damage will occur.

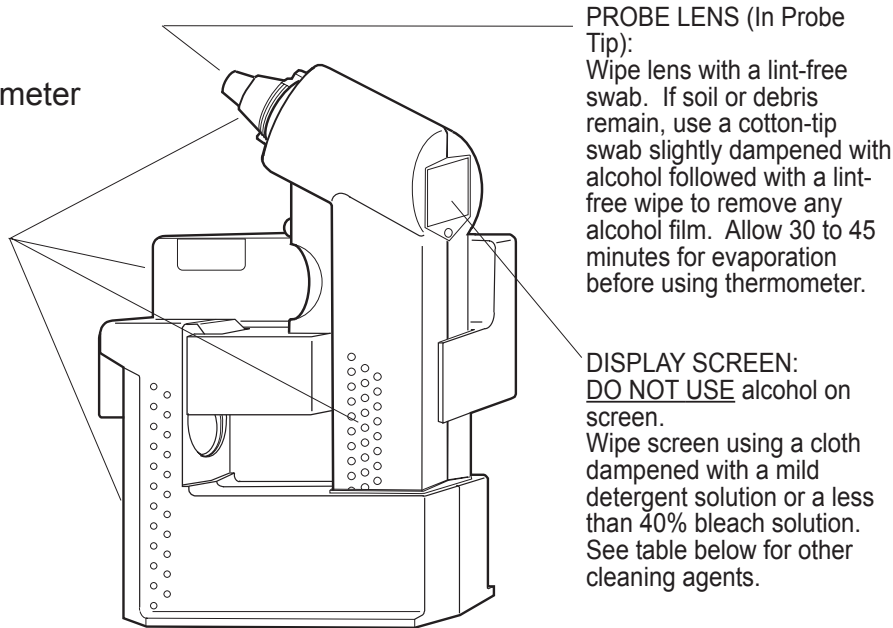
Thermometer Cleaning (Continued)

If a specific cleaning agent or disinfectant is currently used, ALARIS Medical Systems recommends examining chemical ingredients prior to use on the thermometer. If an uncertain cleaning agent or disinfectant is currently being used on the instrument, call ALARIS Medical Systems.

Figure 7

Cleaning of Thermometer

**PROBE TIP/
THERMOMETER/
DISPENSER/HOME
BASE/
WALL MOUNTING
BRACKET (not shown):**
Wipe surfaces using a cloth dampened with mild detergent or a less than 40% bleach solution. See table below for other cleaning agents.



PROBE LENS (In Probe Tip):
Wipe lens with a lint-free swab. If soil or debris remain, use a cotton-tip swab slightly dampened with alcohol followed with a lint-free wipe to remove any alcohol film. Allow 30 to 45 minutes for evaporation before using thermometer.

DISPLAY SCREEN:
DO NOT USE alcohol on screen.
Wipe screen using a cloth dampened with a mild detergent solution or a less than 40% bleach solution. See table below for other cleaning agents.

CAUTION

Only use Isopropanol Alcohol on the lens as directed.
Do not use Alcohol on other parts of the system.

Only use a cloth dampened with one of the following cleaning agents to clean the system. Avoid contact with the lens.

Cleaning Agents	Chemical Base
Ammonium	Quaternaries
Bleach (<40 %)	Chloride/Chlorine
Cidex/Wavicide	Glutaraldehyde
Mild Detergent	Alkali

Service Information

NOTE: If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this manual and the cause cannot be determined, do not use the instrument. Contact qualified ALARIS Medical Systems® service personnel.

Customer Service

Information or assistance may be obtained by calling one of the following Customer Service numbers:

United States	(800) 482-4822
UK:	
Phone	44 1256 388229
Fax	01256 330 860

Technical Support

Technical support, service information, applications, and manuals may be obtained by contacting an ALARIS Medical Systems® representative.

United States	(800) 854-7128, extension 6003
UK, phone	44 1256 388229

When submitting any request for service, include:

- a description of difficulty experienced
- instrument settings
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

Product Return

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), reference the return authorization information, and return it to the appropriate service or distribution center. ALARIS Medical Systems does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

INTERNATIONAL WARRANTY

ALARIS Medical Systems, Inc. (hereinafter referred to as "ALARIS Medical Systems") warrants that:

- A. Each new infusion instrument (pump, controller or peripheral instrument) is free from defects in material and workmanship under normal use and service for a period of two (2) years from the date of delivery by ALARIS Medical Systems to the original purchaser.
- B. Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.
- C. Each Mains Cable, Battery, Flow Sensor (ECD) and non-disposable probe is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.
- D. Each new Thermometer is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical Systems to the original purchaser.

If any product requires repair during the applicable warranty period, the purchaser should communicate directly with its local ALARIS Medical Systems® service centre to determine the appropriate service facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical Systems' expense. The product requiring service should be returned promptly, properly packaged, and postage prepaid by purchaser. Loss or damage in return shipment to ALARIS Medical Systems shall be at purchaser's risk.

In no event shall ALARIS Medical Systems be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical Systems® product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product.

Furthermore, this warranty shall not apply to, and ALARIS Medical Systems shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical Systems® product which has been:

- (A) repaired by anyone other than an authorised ALARIS Medical Systems® service representative;
- (B) altered in any way so as to affect, in ALARIS Medical Systems' judgement the stability or reliability of the product or has had the product's serial or lot number altered, effaced or removed;
- (C) subjected to misuse or negligence or accident; or
- (D) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical Systems.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of ALARIS Medical Systems, and ALARIS Medical Systems neither assumes nor authorises any representative or other person to assume for it any other liability in connection with the sale of ALARIS Medical Systems® products.

ALARIS MEDICAL SYSTEMS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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ALARIS[®]

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U.S. Patent Nos. 4,907,895; 6,332,090; CA Patented/Breveté Nos. 2037775; 2037940; DE D.B.P. No. 446788; GB Patent No. 446788; JP Patent Nos. 特許第 2603003 号; 特許第 2603004 号. Other Patents Pending.